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UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON

JEREMY OLSEN,

Plaintiff,

v.

XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services,

Defendant.

No. 2:21-CV-00326-SMJ

DEFENDANT'S OPPOSITION TO MOTION FOR PRELIMINARY INJUNCTION

Defendant made an unfortunate error in denying the two Medicare claims at issue in this case. Defendant admitted this error in its Amended Answer (ECF No. 16), and has asked that the case be remanded to the Secretary Health and Human Services ("Secretary"). Plaintiff is also entitled to an award of reasonable attorneys' fees and costs under the Equal Access to Justice Act ("EAJA").

However, Plaintiff is not entitled to a nationwide preliminary injunction. As a practical matter, the two claims at issue have already been paid by the Medicare Administrative Contractor responsible for processing Plaintiff's claims. Moreover, there is virtually no chance of a similar error reoccurring in the future because, as of February 28, 2022, Plaintiff's CGM claims will be covered under a Final Rule that the Secretary recently adopted through notice and comment rulemaking.

As a legal matter, the Court lacks jurisdiction to enter the requested injunction. And, even if jurisdiction could be established, the requirements for a preliminary injunction have not been met. Plaintiff is not likely to succeed on the merits of his challenge to CMS 1682-R, and has failed to show actual, imminent harm if an injunction does not issue. Two other district courts have recently declined to enter preliminary inunctions in similar cases, and this Court should do the same.

BACKGROUND

A. Plaintiff's Claims and Procedural History

The Court is familiar with the claims and procedural history of *Olsen v. Becerra*, Case No. 20-CV-00374-SMJ (E.D. Wash.) ("*Olsen I*"), so the Secretary does

not repeat it here, except to note that in *Olsen I* the Plaintiff obtained a judgment ordering coverage of the claim for Medicare coverage of CGM supplies at issue in that case, and that attorney's fees were awarded to Plaintiff at market rates.

This case involves two claims for coverage of CGM supplies (sensors) that were submitted during the pendency of *Olsen I*, and were initially denied by the Secretary.[1] Defendant erroneously rejected these two claims after entry of the Court's decision in *Olsen I,* and has since admitted his error. ECF No. 16 at ¶¶ 3, 6.[2]

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[1] One of these claims received an unfavorable Medicare Appeals Counsel ("MAC") determination, *see* ECF No. 16 at ¶¶ 63–66; the other claim received an unfavorable Administrative Law Judge ("ALJ") decision, and also a denial of a request for expedited access judicial review pursuant to 42 C.F.R. § 405.990, *see id.* ¶¶ 67–90, but had not yet received a final agency decision prior to the filing of this lawsuit. Only a claim that has received a final agency decision can properly be appealed to this Court under 42 U.S.C. § 405(g). *Martin v. Shalala*, 63 F.3d 497, 503 (7th Cir. 1995).

[2] Defendant investigated why Plaintiff's claims were erroneously denied, and determined that an employee of the Medicare Administrative Contractor responsible for processing Plaintiff's claims failed to make a manual adjustment to the submission code assigned to Plaintiff's claims in the contractor's claims processing system that was needed to facilitate payment, as the employee had been instructed to do following this Court's decision in *Olsen I*. *See* ECF No. 16 at ¶ 3.

On information and belief, the Medicare Administrative Contractor ("MAC") responsible for processing Plaintiff's claims has paid the two claims at issue. ECF No. 16 at ¶ 76. The payment date listed in the MAC's records is July 15, 2021. *Id.* The MAC has also paid other claims for CGM sensors submitted by Plaintiff. *See id.*

Plaintiff seeks a preliminary injunction "barring the Secretary from continuing to reject continuous glucose monitor (CGM) claims based on CMS 1682-R and/or the claim that a CGM is not 'primarily and customarily used to serve a medical purpose.'" ECF No. 6 at 1. The requested injunction goes beyond the two claims at issue in this case—which, as noted, have already been paid—and would apply to future claims by Plaintiff and unidentified non-parties that have not yet been submitted and/or properly channeled through 42 U.S.C. § 405(g).

B. CMS Ruling 1682-R and the DME Final Rule

Plaintiff challenges CMS 1682-R, which distinguishes between "therapeutic" or "non-adjunctive" CGMs and "non-therapeutic" or "adjunctive" CGMs. Under CMS 1682-R, only the former category of CGMs, and not the latter, were considered "durable medical equipment" or "DME" and covered by Medicare.

Late last year, the Secretary, through notice-and-comment rulemaking, issued a final rule that **replaces** CMS 1682-R. *See* 86 Fed. Reg. 73,860, 73,860–73,911 (Dec. 28, 2021) (the "DME Final Rule").[3] The DME Final Rule supersedes CMS 1682-R

[3] Plaintiff characterizes the final rule as merely a "proposed new Rule." ECF No. 6 at

with respect to CGM systems and classifies such systems, including so-called "non-therapeutic" or "adjunctive" CGMs, as DME. 86 Fed. Reg. at 73,896–902; *id.* at 73,899 ("We now believe that because adjunctive CGMs ... can provide information about potential changes in glucose levels while a beneficiary is sleeping and is not using a blood glucose monitor, these CGMs … are primarily and customarily used to serve a medical purpose."). Further, with respect to claims submitted for "CGM sensors and transmitters used with insulin pumps"—such as the two claims at issue in this case—the DME Final Rule makes clear that those claims were "being denied inappropriately based on CMS–1682–R even though this Ruling only addressed the classification of CGM receivers as DME and did not address coverage of CGM sensors and transmitters used with insulin pumps." *Id.* at 73,898.

C. Recent Similar Cases and Denials of Injunctive Relief

Two other district courts have rejected similar requests for injunctive relief. In *Lewis v. Becerra*, the putative-class-action plaintiffs sought a preliminary injunction nearly identical to the one requested here. *Lewis v. Becerra*, 2022 WL 123909 (D.D.C. Jan. 13, 2022). The Court denied the motion, finding that "the plaintiffs ha[d] not met their burden to show irreparable harm." *Id.* at *10.

In *Smith v. Becerra*, the Secretary confessed error and asked the Court to enter judgment in the plaintiff's favor and to remand the case to the Secretary for payment

3. But the DME Final Rule is a *final* rule. *See* 86 Fed. Reg. 73,860, available here.

of the three CGM claims at issue in that case. *Smith v. Becerra*, No. 21-CV-47 (D. Utah), ECF No. 51. After the Court entered judgment in plaintiff's favor and remanded the matter to the Secretary (*Id.*, ECF Nos. 52, 53), the plaintiff moved for reconsideration, arguing that she was entitled to broader relief, including an injunction enjoining continued enforcement of CMS 1682-R. *Id.*, ECF No. 54. The Court denied the motion, ruling that "by directing payment of the claims then pending before [the] court, the court [had] granted Plaintiff all of the relief authorized by statute." *Id.*, ECF No. 55 (Feb. 8, 2022 docket order). The Court further noted that the plaintiff was seeking an injunction "to ensure favorable administrative rulings *on other claims currently pending before the Secretary*," which the Court concluded that it lacked jurisdiction to entertain under Section 405(g) because no "final decision[s]" had been rendered. *Id.* (emphasis in original). And, finally, the Court refused to entertain the plaintiff's challenge to CMS 1682-R in light of the DME Final Rule:

> Nor do Plaintiff's concerns that the Secretary may apply a rescinded regulation [CMS 1682-R] to her pending administrative claims rather than a revised regulation [the DME Final Rule] that will take effect on February 28, 2022, create a case or controversy that is ripe for decision by this court. For as the Supreme Court has explained, "a claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *Texas v. United States*, 523 U.S. 296, 300 (1998).

Id. at ECF No. 55.

ARGUMENT

A. The Requested Injunction Is Jurisdictionally Barred.

1. *Plaintiff's Claim for Injunctive Relief is Moot*

Plaintiff's request for a preliminary injunction is moot. A controversy is moot

if complete relief has been obtained and there is no reasonable expectation that the violation will continue into the future. *Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. Vilsack*, 6 F.4th 983, 991 (9th Cir. 2021). Both requirements are satisfied here. First, Plaintiff has received complete relief for the two claims at issue, which were paid by the MAC responsible for Plaintiff's claims before this action was filed. ECF No. 16 at ¶ 76.

Second, there is little chance that Plaintiff's claims will be erroneously denied in the future. As of February 28, 2022, Plaintiff's CGM claims will be covered under the DME Final Rule, which, as noted above, classifies CGM systems, including so-called "non-therapeutic" or "adjunctive" CGMs, as DME, and further clarifies that claims for CGM sensors and transmitters used with insulin pumps *will* be covered.

Under the so-called "voluntary cessation" doctrine, a defendant's cessation of allegedly unlawful conduct does not deprive a court of jurisdiction "unless it can be said with assurance that there is no reasonable expectation that the alleged violation will recur and interim relief or events have completely and irrevocably eradicated the effects of the alleged violation." *Ranchers Cattlemen*, 6 F.4th at 991 (quotation omitted). The government receives greater deference than private parties in this context, *id.*, but "must still demonstrate that the change in its behavior is entrenched or permanent." *Fikre v. FBI*, 904 F.3d 1033, 1037 (9th Cir. 2018).

The instant case meets the *Ranchers Cattlemen* standard and is moot with respect to Plaintiff's claims. Plaintiff's CGM claims submitted to the Secretary as of

the filing of this lawsuit have all been paid by the Secretary's MAC, including the two claims directly at issue in the case, which has eradicated the effects of the alleged violation. ECF No. 16 at ¶ 76. In addition, the Secretary has also promulgated the DME Final Rule. This new rule effectively ensures that future CGM claims submitted by Plaintiff and other similarly-situated Medicare claimants will not be denied on the grounds that a CGM is not DME. Thus, there is no reasonable expectation that the alleged violation will recur with respect to Plaintiff.

Plaintiff asserts, without citation, that the Secretary intends to continue to rely on CMS 1682–R to reject CGM claims for "another year." ECF No. 6 at 3. The regulations promulgated in the DME Final Rule take effect on February 28, 2022. 86 Fed. Reg. at 73,860. Contrary to Plaintiff's assertions, nothing prevents the Secretary from considering the reasoning in the DME Final Rule and applying it to claims with dates of service earlier than February 28, 2022.

Any assertion by Plaintiff that the case is not moot due to the existence of claims by an undefined, putative class of individuals who have not been made parties to this case is insufficient to establish a live case or controversy. The Supreme Court recently addressed this issue in *Genesis Healthcare Corp. v. Symczyk*, 569 U.S. 66 (2013). The plaintiff in *Genesis* was an individual employee who sought relief under the Fair Labor Standards Act on behalf of herself and other "similarly situated" individuals. Like the instant case, the *Genesis* case had not been certified as a class action. During the course of the litigation, the individual plaintiff's claims were

resolved. *Id.* at 69. The Court held that the case did not remain justiciable based on the collective-action allegations in the complaint; instead, the lawsuit "became moot when [the plaintiff's] individual claim became moot, because she lacked any personal interest in representing others in this action," and because "the mere presence of collective-action allegations in the complaint cannot save the suit from mootness once the individual claim is satisfied." *Id.* at 73; *see also U.S. v. Sanchez-Gomez*, 138 S. Ct. 1532, 1540 (2018).

2. *42 U.S.C. § 405(h) bars the injunctive relief Plaintiff seeks.*

Even if the Court determines that Plaintiff's request for injunctive relief is not moot, the Court lacks jurisdiction to order the relief sought. The judicial-review provision in the Medicare statute incorporates that of the Social Security Act. 42 U.S.C. §§ 1395ff(b)(1)(A), 1395ii. "That statute, in turn, provides an *exclusive mechanism* for review of the agency's decisions, expressly displacing the general federal-question jurisdiction of 28 U.S.C. § 1331." *Odell v. U.S. Dep't of Health & Hum. Servs.*, 995 F.3d 718, 722 (9th Cir. 2021) (emphasis added; citing 42 U.S.C. § 405(h)). It states that "[a]ny individual, after any final decision of the [Secretary of Health and Human Services] made after a hearing to which he was a party, ... may obtain a review of such decision by a civil action." 42 U.S.C. § 405(g); *see id.* § 1395ff(b)(1)(A). A "critical feature of section 405(g) is that it permits review only 'after any final decision' of the agency." *Odell*, 995 F.3d at 722.

In *Odell*, the Ninth Circuit vacated a preliminary injunction entered in a

Medicare case because the plaintiff had not satisfied section 405(g)'s presentment requirement for his claims, but instead was seeking "to obtain prospective relief" from the application of a Local Coverage Determination policy to his "future claims." *Odell*, 995 F.3d at 723. The Court of Appeals explained that the district court lacked "subject-matter jurisdiction over those claims because [the plaintiff had] not yet presented them to the Secretary for a final decision." *Id.* (citations omitted).

Finally, Plaintiff's reliance on *Blue Cross & Blue Shield Ass's v. Shalala*, 1996 WL 636131 at *3 (D.D.C. Aug. 27, 1996), for the proposition that "courts frequently enjoin agencies from enforcing regulations that have been found to be invalid" is misplaced. ECF No. 6-1 at 3. That statement may be true, but that case was not a Section 405(g) case (nor were any of the cases it cites), and thus is inapplicable here.

B. Plaintiff Fails To Meet The Standard For Injunctive Relief

To obtain a preliminary injunction, Plaintiff must show that he is likely to prevail on the merits of his claims. *All. for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1131 (9th Cir. 2011). Plaintiff cannot meet that requirement for three reasons.

First, section 405(g) does not provide for injunctive relief; it only allows the Court to enter a judgment "affirming, modifying, or reversing the decision" of the Secretary with respect to the claims for Medicare reimbursement at issue. 42 U.S.C. § 405(g). *Second*, to the extent Plaintiff is seeking relief for other non-parties, his claims are barred by 42 U.S.C. § 405(h), as incorporated by § 1395ii. *See Smith, supra* (ECF No. 55) (court "has no jurisdiction over [other claims pending before the

Secretary], which have not yet resulted in "final decision[s]" within the meaning of Section 405(g)"). *Third*, Plaintiff's challenge to CMS 1682-R will be moot as of February 28, 2022, when the DME Final Rule takes effect. *See id.* ("Plaintiff's concerns that the Secretary may apply a rescinded regulation [CMS 1682-R] to her pending administrative claims rather than a revised regulation that will take effect on February 28, 2022, [do not] create a case or controversy that is ripe for decision by this court.").

Plaintiff must also show that he would be irreparably harmed if a preliminary injunction does not issue. *Cottrell*, 632 F.3d at 1131. Irreparable harm is lacking for many of the same reasons. All of Plaintiff's outstanding CGM claims have been paid by the Secretary's MAC. ECF No. 16 at ¶ 76. The DME Final Rule, as well as the *res judicata* effect of this Court's judgment in *Olsen I*, ensures that Plaintiff's future claims will not be rejected on the grounds he seeks to enjoin the Secretary from relying upon. Plaintiff cannot show any harm that is actual and imminent, as opposed to conjectural or hypothetical. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 103 (1998).

Finally, Plaintiff cannot satisfy the irreparable harm requirement by relying on alleged irreparable harm to other, differently situated, non-parties. *Lewis*, 2022 WL 123909, at *9 (denying preliminary injunction like that sought here on ground that, *inter alia*, plaintiffs "have not introduced any medical evidence" to support a finding of irreparable harm as to putative class members). The motion should be denied.

DATED this 22nd day of February, 2022.

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CERTIFICATE OF SERVICE

I hereby certify that on February 23, 2022, I caused to be delivered via the method listed below the document to which this Certificate of Service is attached (plus any exhibits and/or attachments) to the following:

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